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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,294	08/24/2001	Gregory J. Hinkle	16517.253	1056

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EXAMINER

BUI, PHUONG T

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

**Application No.**

09/938,294

**Applicant(s)**

HINKLE ET AL.

**Examiner**

Phuong T. Bui

**Art Unit**

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/1403.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5,8-10 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-10 and 14-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The Office acknowledges the receipt of Applicant's amendment filed October 14, 2003. Claims 1-5, 8-10 and 14-18 are pending and are examined in the instant application. This action is made FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any previous objections or rejections not addressed below have been withdrawn.

#### ***Claim Rejections - 35 USC § 101 Utility***

3. Claims 1-5, 8-10 and newly added claims 14-18 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility. This rejection is maintained for reasons of record. Applicant traverses, stating that 1) "to develop nutritionally and agriculturally enhanced crops and products" and "aid gene expression studies that allow the dissection and elucidation of commercially useful traits" comply with the utility requirements; and 2) the uses set forth are analogous to a microscope and golf club in that a utility generic to a broad class of molecules does not compromise the specific utility of an individual member of that class. Applicant's traversals have been considered but are deemed unpersuasive for the following reasons. While all microscopes and golf clubs have a well-established utility, Applicant's gene sequence of unknown function does not have a well-established utility. Thus, Applicant's asserted utility must be assessed. For a claimed invention to have asserted utility under current utility guidelines, its asserted utility must be credible, specific and substantial. As stated

in the previous Office action, the claimed invention fails to meet the specific and substantial requirements. That is, Applicant's gene does not belong in a specific class of genes (for example, a phosphorylase enzyme); and the use set forth is not deemed to be sufficiently substantial such that one skilled in the art can readily use the invention in a real-world sense (for example, expression of the gene renders the plant disease resistant). One phosphorylase gene does not compromise the utility of another phosphorylase gene; and likewise, one disease resistance gene does not compromise the utility of another disease resistance gene. Such is not the case here. Applicant's gene is not specific to any particular class—to say that a gene belongs to the gene class does not define the class of genes. Further, not all genes have utility because the functions of many genes are not known, unlike microscopes and golf clubs, and one skilled in the art would not be able to use a gene of unknown function to achieve real-world benefits without further research. When a claimed invention lacks specific and substantial utility, the credibility requirement of utility cannot be assessed. Accordingly, the rejection is maintained.

***Claim Rejections - 35 USC § 112, first paragraph***

4. Claims 1-5, 8-10 and newly added claims 14-18 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. This rejection is maintained for reasons of record. Applicant's traversals have been addressed above.

***Claim Rejections - 35 USC § 112, second paragraph***

5. Claims 1-5, 8-10 and newly added claims 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained for reasons of record. With regard to “substantially purified”, Applicant traverses that page 8, lines 20-26 of the specification defines the phrase in a manner free of circularity or indefiniteness. The Office has determined the definition given in the specification as indefinite at the previous Office action. Unless Applicant specifically indicates why page 8, lines 20-26 would render the phrase definite, this rejection is maintained.

With regard to “structural nucleic acid molecule”, Applicant traverses that one skilled in the art would readily recognize the distinction between a structural nucleic acid molecule and a non-structural nucleic acid molecule. Applicant’s traversal is unpersuasive because every nucleic acid molecule has a structure. The specification does not indicate how a structural nucleic acid molecule differs from a non-structural nucleic acid molecule. Applicant provided no evidence that the state of the art at the time the invention was made would readily recognize the distinction. Accordingly, this rejection is maintained.

***Remarks***

6. No claim is allowed. SEQ ID NO:2 encoding SEQ ID NO:45 is free of the prior art.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1638

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (703) 305-1996.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Phuong Bui  
Primary Examiner  
December 23, 2003



PHUONG T. BUI  
PRIMARY EXAMINER